

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/559,995 Confirmation No. 4575  
Applicant : Kanikanti et al.  
Filed : August 7, 2007  
Title : Tablets containing enrofloxacin and flavoring agents and/or  
flavors  
Group Art Unit : 1619  
Examiner : Raymond Yeager

VIA EFS

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION OF VENKATA-RANGARAO KANIKANTI  
UNDER 37 C.F.R. §1.132

Dr. Venkata-Rangarao Kanikanti declares and states as follows:

1. I received a Master in Pharmacy degree from Mysore University, in India. Thereafter, I received a Doctorate in Pharmacy from the University of Panjab in India.
2. From January 1989 to date, I have been employed by Bayer. My present position is Laboratory Manager.
3. Under my direction and control, a study to compare the tablet of the present invention (uncoated tablet that includes enrofloxacin, lactose, microcrystalline cellulose, and other excipients, Batch No. 1165 on the graph attached) vs. a tablet having standard ingredients (exchange of microcrystalline cellulose and lactose for maize starch – all other ingredients are the same, Batch No. 1164 on the graph attached) was conducted. The exact formulation for the tablets tested is attached in

tablet form herewith. Maize starch is a common filler for tablets. In addition, it is considered to have an advantage over lactose in that it also acts as a disintegrant. The tablets were compared for their crushing strength and friability at different compression forces.

4. For the tablet of the present invention, that includes microcrystalline cellulose and lactose, has a considerably higher crushing strength and lower friability than the maize starch tablet.
5. The tablets were tested according to the USP friability test which is used to determine the abrasion resistance (= friability) of tablets. The abrasion is required to be below 1% by the United States Pharmacopeia (See USP 23, page 1981, attached herewith for testing method and range).
6. For the tablet of the present invention, no abrasion was detected. For the maize tablets made with a compression force of 10 and 20 kN, they broke in the abrasion test. For the maize starch tablets made with 30 kN, they have an abrasion of 7.66%, which is unacceptable (higher than 1% allowed).
7. As can be observed based on these results, the significant difference between crushing strength and friability is not anticipated based on changing maize starch, a common filler, to microcrystalline cellulose and lactose. It is surprising that a combination of microcrystalline cellulose and lactose made the tablet perform so well.
8. The applicant further declares that all statements made herein are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false

statements may jeopardize the validity of the application or any patent  
issuing therefrom.

K.V. Kanikanti

Dr. Venkata-Rangarao Kanikanti

26/10/2010

Date

1995

USP 23

NF 18

THE UNITED STATES PHARMACOPEIA

THE NATIONAL FORMULARY

*By authority of the United States Pharmacopoeial  
Convention, Inc., meeting at Washington, D.C.,  
March 8-10, 1990. Prepared by the Committee of  
Revision and published by the Board of Trustees*

*Official from January 1, 1995*



010000005993

Kekulé-Bibliothek

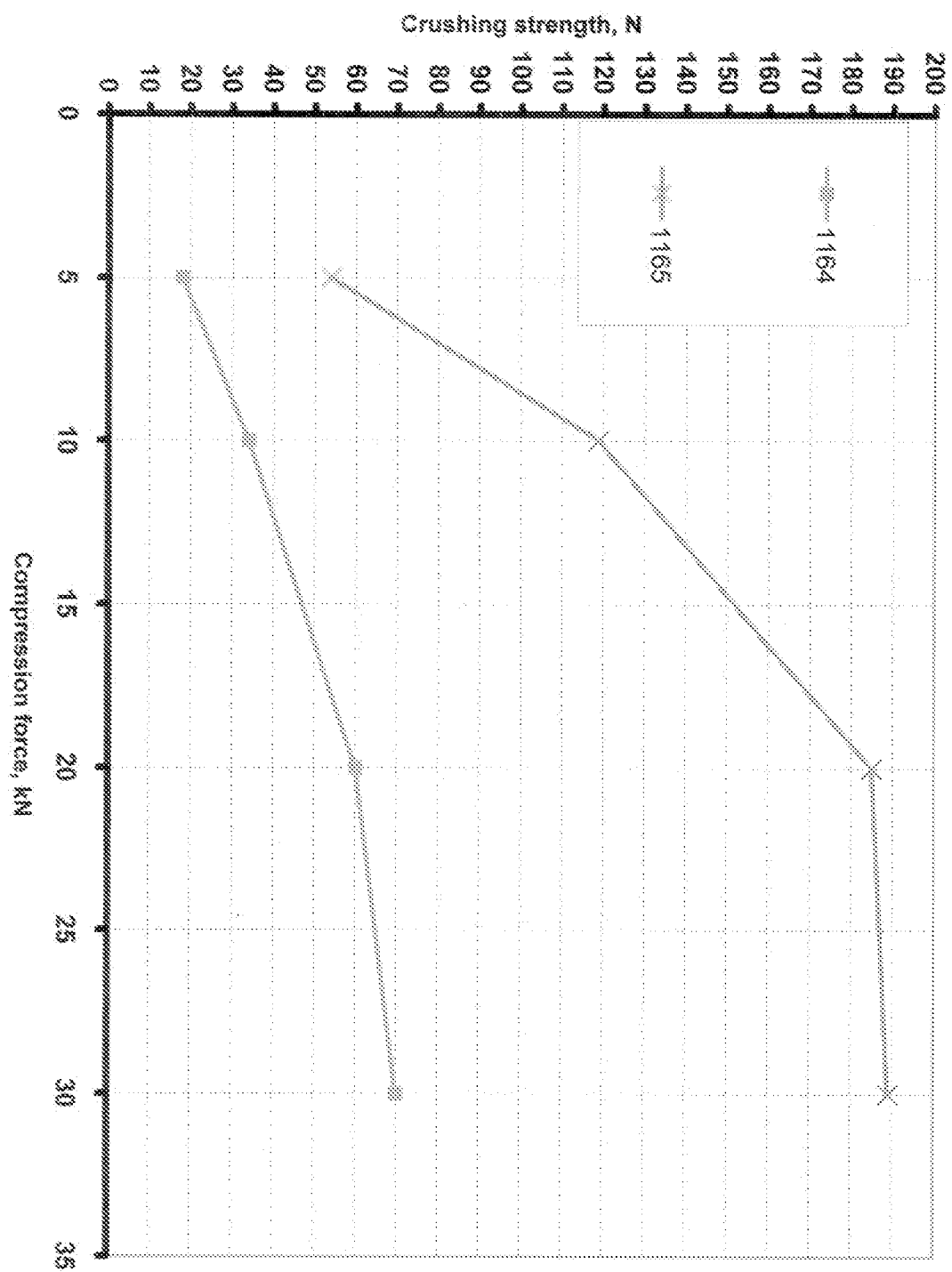
VT-E



UNITED STATES PHARMACOPEIAL CONVENTION, INC.  
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\* American National Standards Institute, 1430 Broadway, New York, NY 10018.



Attachment A

The composition of the two formulations is as follows:

	<b>1164</b> (% w/w)	<b>1165</b> (% w/w)
Enrofloxacin	20	20
Lactose monohydrate	----	35
Microcrystalline cellulose	-----	10
Maize starch	52	7
Povidone 25	5	5
Artificial beef flavor	20	20
Colloidal silicon dioxide	2.0	2.0
Magnesium stearate	1.0	1.0

The ingredients are mixed well and passed through a 1 mm screen manually and then compressed into tablets weighing 750 mg using tools of oblong shape (18 mm length and 8 mm width with one score). The compression force was varied as shown in the diagram attached. The samples collected at each compression were tested for tablet hardness and friability as described by the USP.

**Determination of the crushing strength:**

The tablets are placed between the jaws of the hardness tester (Machine type: Schleuniger 6D hardness tester) in such a way that the tip of the capsule shape will be in contact with the jaws when the jaws move. The force in Newtons required to crush the tablets is noted. This is a routine procedure done by the skilled person in the art for determining the tablet hardness with Schleuniger hardness tester.